ISSUE
The Belgian Competent Authority has prepared a favourable initial opinion on an application for the authorisation of Nattokinase, as a novel food ingredient, under the Novel Foods Regulation (EC) No 258/97. The Committee are asked whether they agree with the initial opinion and whether they would like to make any further comments on this application. The Committee’s advice will form the basis for the UK’s formal response to the Commission.

Background
1. On 6 January, the European Commission forwarded the Belgian Competent Authority’s (CA) initial opinion on an application made by Japan Bio science Laboratory under Article 4 (1) of Regulation (EC) 258/97, for the authorisation of Nattokinase. The Commission has requested the views of Member States on the Belgian CA’s initial opinion. Member States have until 3 March to submit any comments and/or reasoned objections to the Belgian assessment.

2. The application dossier is attached as Annex A, and the Belgian Initial Assessment Report is attached as Annex B; Annexes A and B contain protected information.

This application
3. Nattokinase is a purified extract of natto, a traditional Japanese food, also marketed in the EU, which is obtained by the fermentation of soya beans using the bacterium Bacillus subtilis var natto. Despite its name nattokinase is not a kinase enzyme, but is regarded as having fibrinolytic qualities.

4. The Japanese applicant intends to market the novel ingredient in food supplements, as capsules (sort gel capsules and hard shell capsules), tablets and powder. The dosage takes into account risk groups that take blood thinners as medicines. The target population for NSK-SD® (Natural Super Kinase-Sprayed-Dried) is healthy men and women who want to maintain healthy whole blood viscosity and who have risk factors such as a BMI over 30kg/m², age and/or a slight increase in levels of cholesterol.

5. In a double-blind, placebo-controlled study in healthy volunteers (individuals who presented some risk factors eg BMI, age and/or a slight increase in...
cholesterol levels) no side effects were found after 4 weeks. A study conducted in patients who had suffered an ischaemic cerebrovascular accident and were being treated with heparin and platelet aggregation inhibitors, which looked at the safety of simultaneously taking Nattokinase over seven days, showed there was an effect on the coagulation process and a number of minor side effects. A double-blind, placebo controlled study over 6 months in 60 adults with cardiovascular disease being treated with warfarin showed there was an effect on the coagulation process and there were no side effects identified.

6. The novel food is also promoted for long term use. The applicant had not shown Nattokinase was proven to be safe over the long term as no study has been undertaken. Those patients whose coagulation process had been affected by medication or disease should only take this novel ingredient under medical supervision. The applicant proposed labelling to indicate that individuals taking anti-coagulant or blood pressure medication, or those with a history of bleeding tendency or conditions associated with bleeding, should be supervised by health professionals.

7. The main ingredient is Nattokinase which is produced from soybeans. It is very likely to cause allergic reactions in those allergically sensitised to Soy.

8. The ACNFP reviewed an application on Nattokinase at its November 2012 meeting. The relevant section of the minutes of the meeting state:

   The Committee’s concerns regarding the safety of nattokinase related to a lack of safety data, in particular its potential enzymic effect in the GI tract. Members noted that, despite its name, nattokinase is not a kinase but a protease enzyme and that its effect, for example, on mucous membranes needed to be investigated thoroughly.

9. Under Section 4 of the European Commission’s Scientific Committee on Food (SCF) Recommendation 97/618/EC the classification of this novel food is 2.1; the source of the novel food has a history of food use in the community.

COMMITTEE ACTION REQUIRED

10. Members are asked whether they agree with the initial opinion from the Belgian Authorities and whether they wish to make any comments on the application.

11. The Committee’s advice will form the basis for the UK’s formal response to the opinion of the Belgian Competent Authority.

   Secretariat
   January 2015
Annexes attached:

**Annex A**  Application for the approval of Nattokinase (Annexes to the paper are available on request)

**Annex B**  Initial Opinion of the Belgian Authorities